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Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/486,971 05/19/00 LEHTOLA

V 933-154FCT

002292 HM22/0301
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EXAMINER

BENNETT, R

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/486,971

Applicant(s)

LEHTOLA ET AL.

Examiner

Rachel M. Bennett

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Examiner acknowledges receipt of Amendment B filed 1/24/01.
2. Claims 1-9, and 11 are pending.

Specification

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 9 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Posti et al (US 5525354).

Posti discloses a pharmaceutical preparation for oral use containing a pharmacologically acceptable salt of a dichloromethylene bisphosphonic acid, a clodronate, especially disodium clodronate (see abstract, column 1 lines 6-10). The preparation may also contain additives, such as carriers, diluents, fillers, lubricants, and disintegrating agents, which are all known in the art (see column 2 lines 18-22). More specifically, microcrystalline cellulose as a filler and colloidal silicon dioxide may be used as a lubricant (see column 2 lines 41-51). The preparation is carried out using known tableting, granulating or pelletization techniques (see column 2 lines 52-54). Example 1 illustrates a tablet comprising disodium clodronate, microcrystalline cellulose and silicon dioxide. The desired amount of clodronate can vary within wide limits from 10 to 95% by weight (see column 2 lines 22-25). The preparation also comprises of silicified

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microcrystalline cellulose comprises about 8 to 20% by weight, and lubricants and/or disintegrants comprise about 0.5 to 10% by weight (see example 1). Therefore these claims are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Posti et al. (US 5525354).

Posti, as disclosed above, teaches a pharmaceutical preparation containing the active ingredient disodium chodronate with an enteric coating. Posti does not specifically teach the process of dry granulation.

It is the position of the examiner that it would be obvious to one of ordinary skill in this art, at the time of invention, by routine experimentation, to omit the water and/or ethanol from the preparation in order to achieve the applicant's goal of dry granulation because the reference teaches the preparation is carried out using known granulating techniques and dry granulation is well known in the art (see column 2 lines 40-54). The reference also desires a tablet with an enteric coating. Applicant's claims do not exclude the addition of an enteric coating. The expected result would be pharmaceutical preparation containing the active ingredient disodium

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clodronate with silicon dioxide and microcrystalline cellulose and lubricants and/or disintegrating agents in order to provide an oral solid dosage form compressed into a tablet.

Art of Interest

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sherwood et al. WO 96/21429 discloses microcrystalline cellulose particles and silicon dioxide in an agglomerate used as an excipient.

Response to Arguments

8. Applicant's arguments filed 1/24/01 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus, claims 1-7, 9 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Posti et al (US 5525354) and Claims 1-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Posti et al. (US 5525354).

Applicants argue that Posti does not teach a smaller tablet size and better powder flow. However, applicant's arguments are not being claimed. The examiner refers to the teaching of Posti at col. 1 lines 21-27 discloses a smaller tablet than the prior art and a lubricant at col. 2 lines 15-22.

Applicants also argue that Posti does not teach silicified microcrystalline. However, applicants define silicified microcrystalline cellulose as an excipient by copressing microcrystalline cellulose and silicon dioxide, with no chemical interaction between the two components. Therefore applicant gains no advantage or unexpected result by using silicified microcrystalline cellulose over admittedly prior art mixture. It is noted the reference teaches wet

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granulation technique in col. 2 lines 50-54. The prior art use of wet granulation inherently produces silicified microcrystalline cellulose.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett:RMB
February 28, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600